FEB 2 3 2012

# TORNIER

## Summary of Safety and Effectiveness information
## *510(k) Premarket Notification – KNEETEC PFJ*

Date prepared: November 4th, 2011

**Regulatory authority:** Safe Medical Devices Act of 1990, 21 CRF 807.92

### 1) Device name

| | |
|---|---|
| **Trade name:** | **KNEETEC PFJ & HLS KNEETEC patellar component** |
| **Common name:** | Patellofemoral knee prosthesis |
| **Classification name:** | 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis |

### 2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier – France

### 3) Appliquant

Tornier
7701 France avenue South
Suite 600
Edina MN 55345 – USA

### 4) Company contact

Tornier
Mrs Stéphanie BERNARD
Regulatory Affairs Specialist
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: + 33 (0)4 76 61 35 00
Fax: + 33 (0)4 76 61 35 59
e-mail: stephanie.bernard@tornier.fr

### 5) Classification

| | |
|---|---|
| **Device class:** | Class II |
| **Classification panel:** | Orthopedic |
| **Product code:** | 87 KRR |

### 6) Equivalent / Predicate device

**Avon Patello-Femoral Joint Prosthesis,** Howmedica Osteonics Corp, K010100, K020841, K041160, K051948
**Patello-Femoral Knee Implant,** Journey, Smith & Nephew, Inc, K051086
**HLS Kneetec,** Tornier, K094013



TORNIER S.A.S.
161, rue Lavoisier - Montbonnot
38334 SAINT-ISMIER CEDEX
FRANCE

Tél. : 33 (0)4 76 61 35 00
Fax : 33 (0)4 76 61 35 33

S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

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## 7) Device description

The Kneetec PFJ is a semiconstrained resecting prosthesis intended for replacement of the patellofemoral joint. The prosthesis consists of two components, both for cemented use only: a femoral implant and a patella. The patella of the knee joint may be resurfaced with the HLS KNEETEC patellar component (found substantially equivalent in K094013) or KNEETEC PFJ patellar implant.

## 8) Materials

The femoral implant is manufactured from chromium cobalt alloy (CoCr) according to ISO standard 5832-7 or 5832-12. The patella is made of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.

## 9) Indications for use

The replacement of the patellofemoral joint with the KNEETEC PFJ device is indicated in the case of symptoms and serious signs affecting daily activities involving the joint:

- Serious degenerative arthritis of the patellofemoral joint,
- Failure of conservative procedures (realignment, arthroscopy, transfer of the tibial tuberosity) with the persistence of joint pain or dysfunction,
- Patellofemoral dislocation (dysplastic or other origin),
- Post-traumatic arthritis (patellar fracture).

The KNEETEC PFJ patellofemoral prosthesis is intended for cemented use only.

When used in association with the KNEETEC PFJ prosthesis, the patellar component of the HLS KNEETEC has the above mentioned indications for use.

## 10) Summary of technological characteristics

| Main features or system characteristics | | Kneetec PFJ | HLS Kneetec | Avon | Journey |
|---|---|---|---|---|---|
| Materials | Femoral part | CoCr alloy<br>ISO 5832-7<br>or<br>ISO 5832-12 | CoCr alloy<br>ISO 5832-7<br>or<br>ISO 5832-12 | CoCr alloy<br>- | Oxinium<br>- |
| | Patellar component | UHMWPE<br>ISO 5834-2 | UHMWPE<br>ISO 5834-2 | UHMWPE<br>- | UHMWPE<br>ASTM F 648 |
| Method of fixation | | Cemented | Cemented | Cemented | Cemented |
| Intended use | | Replacement of the patellofemoral joint | Total knee prosthesis | Replacement of the patellofemoral joint | Replacement of the patellofemoral joint |
| Terminal sterilization | | Gamma | Gamma | N/K | N/K |
| Manufacturer | | TORNIER | TORNIER | Stryker | Smith & Nephew |
| K-number | | K111970 | K094013 | K010100<br>K020841<br>K041160<br>K051948 | K051086<br>K951987 |



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## 11) Non-clinical testing

The following non-clinical testing has been performed on the smallest components of the ranges (worst case):

- Contact area and trajectories of the patella to compare the congruence of the patella with the trochlea,
- Contact pressure test,
- Measurement of the subluxation force.

Results: there is no significant difference between the results for Kneetec PFJ prosthesis and the predicate devices.

The results of engineering studies referenced in this 510(k) submission demonstrate the Kneetec PFJ is substantially equivalent to the predicate devices.

## 12) Substantial equivalence conclusion

Substantial equivalence of the Kneetec PFJ to the already cleared Avon, Journey and HLS Kneetec prostheses can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The components of the Kneetec PFJ have been compared to the predicate devices.
- The components of the Kneetec PFJ have the same intended use as the Avon and Journey prostheses and very similar indications for use.
- Major technological characteristics are equivalent between the Kneetec PFJ and the predicate devices:
  - Equivalence of general features and material,
  - Equivalence of non-clinical testing results,
  - Equivalence of range of motion,
  - Equivalent means of fixation,
  - Equivalent prosthetic dimensions.

Therefore, in light of the above information, the company believes that the components of the Kneetec PFJ and the patellar component of the HLS Kneetec may be cleared via the 510(k) notification process for use as a Patellofemoral Knee Prosthesis.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tornier, Incoporated
% Ms. Stéphanie Bernard
Regulatory Affairs Specialist
161, rue Lavoiser - Montbonnot
38334 SAINT-ISMIER CEDEX
FRANCE

FEB 2 3 2012

Re: K111970
Trade/Device Name: Kneetec PFJ & HLS Kneetec Patellar Component
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: February 10, 2012
Received: February 13, 2012

Dear Ms. Bernard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known): K111970** K111970

**Device Name:** KNEETEC PFJ

**Indications For Use:**

The replacement of the patellofemoral joint with the KNEETEC PFJ device is indicated in the case of symptoms and serious signs affecting daily activities involving the joint:
- Serious degenerative arthritis of the patellofemoral joint,
- Failure of conservative procedures (realignment, arthroscopy, transfer of the tibial tuberosity) with the persistence of joint pain or dysfunction,
- Patellofemoral dislocation (dysplastic or other origin),
- Post-traumatic arthritis (patellar fracture).

The KNEETEC PFJ patellofemoral prosthesis is intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

# Indications for Use

**510(k) Number (if known): K094013** K111970

**Device Name:** HLS KNEETEC patellar implant

**Indications For Use:**

The HLS KNEETEC is indicated for use as a total knee replacement for the relief of pain and significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis. This device is also intended for the revision of knee prostheses.

The HLS KNEETEC is intended for cemented use only.

When used in association with the KNEETEC PFJ prosthesis, the patellar component of the HLS KNEETEC has the following indications for use:

The replacement of the patellofemoral joint with the KNEETEC PFJ device is indicated in the case of symptoms and serious signs affecting daily activities involving the joint:
- Serious degenerative arthritis of the patellofemoral joint,
- Failure of conservative procedures (realignment, arthroscopy, transfer of the tibial tuberosity) with the persistence of joint pain or dysfunction,
- Patellofemoral dislocation (dysplastic or other origin),
- Post-traumatic arthritis (patellar fracture).

The KNEETEC PFJ patellofemoral prosthesis is intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Millerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices